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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,290	08/03/2001	David M. Goldenberg	018733-1012	5316

26633 7590 09/13/2004

HELLER EHRMAN WHITE & MCAULIFFE LLP  
1666 K STREET,NW  
SUITE 300  
WASHINGTON, DC 20006

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/921,290	<b>Applicant(s)</b> GOLDENBERG, DAVID M.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on June 16, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

## **DETAILED ACTION**

### ***Response to Amendment and Arguments***

1. Claims 1-48 are pending.

Claim 4 has been amended.

Claims 1-48 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. Applicant's claim for domestic priority under 35 U.S.C. 112 is acknowledged. The first action on the merits (FAOM) mailed December 16, 2003 set forth that the priority afforded to all claims was the effective filing date of the instant application filed August 3, 2001, see page 2, paragraph 3. Applicants retort that the Examiner has put forth a blanket denial of priority for all claims, which is improper and should be withdrawn. This argument has been carefully considered, but found unpersuasive.

Claims are separately assessed for their priority. Claims which depend upon independent claims are granted the priority date of the independent claims. In the instant case the all the dependent claims stem from independent claims that include limitations not supported by the priority documents, 09/038,955, filed March 12, 1998, now U.S. Patent number 6,183,744, which is a continuation in part of 09/307,816, filed May 10, 1999, now U.S. Patent number 6,306,393. Accordingly, the priority afforded to

the examined claims is the effective filing date of the instant application, August 3, 2001.

#### ***Oath/Declaration***

4. The oath or declaration continues to be defective for the reasons noted in the FAOM, page 3, paragraph 5.

#### ***Withdrawn Rejections***

##### ***Claim Rejections - 35 USC § 112***

5. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendment to the claim.

##### ***Claim Rejections - 35 USC § 102***

6. The rejection of claims 1, 3-5, 9, 11, 12, 16, 19-22, 26, 39-41, 43 and 46 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,776,456 (filed June 7, 1995) set forth in the FAOM on page 4, paragraph 8 is withdrawn.

#### ***Double Patenting***

7. The rejection of 1-12, 14-27, 32, 37-39 and 41-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent number 6,306,393 (issued October 23, 2001) is withdrawn.

8. The rejection of 1-12, 14-27 and 32-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent number 6,306,393 (issued October 23, 2001), in view of U.S. Patent number 5,837,242 (May 14, 1996) is withdrawn.

9. The rejection of 1-12, 14-28, 32, 37-39 and 41-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent number 6,306,393 (issued October 23, 2001), in view of Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992) is withdrawn.

10. The rejection of 1-12, 14-27, 32, 37-39 and 41-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-13, 15-19 and 23 of U.S. Patent number 6,183,744 (issued February 6, 2001) is withdrawn.

11. The rejection of 1-12, 14-27 and 32-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-13, 15-19 and 23 of U.S. Patent number 6,183,744 (issued February 6, 2001), in view of U.S. Patent number 5,837,242 (May 14, 1996) is withdrawn.

12. The rejection of 1-12, 14-28, 32, 37-39 and 41-48 under the judicially created

doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent number 6,183,744 (issued February 6, 2001), in view of Rybak et al. (Proc. Nat. Acad. Sci. USA 89:3165-3169, April 1992) is withdrawn.

### ***New Grounds of Objection***

#### ***Claim Objections***

13. Claim 30 is objected to because of the following informality: it seems to improperly depend from claim 29 and should depend from claim 26. The 103(a) art rejection reflects the proper dependency.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 102***

14. Claims 1, 2, 8, 9, 11, 12, 16, 19-22, 23, 24, 26 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,776,456 (filed June 7, 1995). Applicant defines domestic animals as companion animals including subhuman primates such as monkeys, see page 16 of the specification, sections 0048 and 0049. In view of that definition the following rejection is set forth. Patent '456 discloses a method of treating a B cell disorder, particularly B cell lymphoma in cynomolgus monkeys, see column 24, line 9-column 28, line 48.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-5, 7-9, 11, 12, 15-29, 32-35 and 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of U.S. Patent number 5,837,242 (May 14, 1996) and Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992). The teachings of patent #5,776,456 have been presented in the 102(e) rejection. U.S. Patent '456 does not teach a method for treating a B-cell or plasma-cell disorder in a domestic animal, such as a dog, cat or horse comprising administering to said animal a therapeutic composition comprising a pharmaceutically acceptable carrier an antibody component, wherein said component is an immunoconjugate composition including radionuclides, RNase toxin immunoconjugate and chemotherapeutic agents, as well as the administration of multiple antibodies. Additionally, patent '456 also does not teach wherein the antibody component comprises a bispecific antibody with an arm that is specific for a low-molecular weight hapten with an attached therapeutic agent.

However, U.S. Patent number 5,776,456 teaches the administration to human patients of therapeutic compositions comprising radiolabeled chimeric antibodies, wherein the radioisotope is yttrium 90 or diagnostic radionuclide indium 111; the

combination of antibodies, for instance a dose imaging radiolabeled anti-CD20 antibody (I2B8) and immunologically active, chimeric anti-CD20 antibody (C2B8); and chemotherapeutic agents such as doxorubicin and prednisone, see column 9, line 6-column 6, line 18; column 13, lines 25-33; and section V spanning columns 31 and 32. Rybak teaches the use of chimeric antibodies linked to toxins such as RNase to target tumor cells, see page 3165, abstract and introduction. And patent '242 teaches the use of bispecific antibodies in the recruitment of powerful effector functions of cytotoxic T cells or natural killer (NK) cells, as well as a tool for imaging, see patent '242, column 20, lines 61-63; column 21, lines 15-30. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the different combinations of the therapeutic compositions as anti-cancer medicaments for any primate animal. It would have been *prima facie* obvious to add a RNase toxin to the taught antibody composition because the cytotoxic potential of the toxin is increased and functional experiments have proven tumor growth inhibitory activity. Furthermore, it would have been *prima facie* obvious to couple a bispecific antibody with a pharmaceutically acceptable carrier in order to treat a B cell disorder in an animal. One of ordinary skill in the art would have been motivated to manufacture such a medicament in order to treat non-human primates such as a monkey companion animal, as well as other domestic or companion animals because the patent sets forth that the disclosed treatment of B cell lymphomas targeting the CD20 antigen is not limited to non-human primates, see patent '456, column 5, lines 7-10.



17. Claims 1-27, 31 and 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of U.S. Patent 6,217,869 (filed September 5, 1997). The teachings of patent #5,776,456 have been presented in the 102(e) rejection. U.S. Patent '456 does not teach a method for treating a B-cell, plasma-cell disorder or autoimmune diseases in a domestic animal comprising administering to said animal a therapeutic composition comprising a pharmaceutically acceptable carrier an antibody component, wherein said component is an immunoconjugate composition including cytokines, radionuclides and chemotherapeutic agents, as well as the administration of multiple antibodies.

However, U.S. Patent number 5,776,456 teaches the administration to human patients of therapeutic compositions comprising radiolabeled chimeric antibodies, wherein the radioisotope is yttrium 90 or diagnostic radionuclide indium 111; the combination of antibodies, for instance a dose imaging radiolabeled anti-CD20 antibody (I2B8) and immunologically active, chimeric anti-CD20 antibody (C2B8); and chemotherapeutic agents such as doxorubicin and prednisone, see column 9, line 6-column 6, line 18; column 13, lines 25-33; and section V spanning columns 31 and 32. And patent number 6,217,869 teaches diagnostic or therapeutic agents including radionuclides (i.e. fluorescence emitters and X-ray emitters), drugs, anti-tumor agents, toxins (i.e. chemotherapeutic agents) and the like, as well as the use of haptens for the treatment of cancer and autoimmune diseases, such as rheumatoid arthritis, see patent '869, column 3, lines 11-25; column 4, lines 53-57; column 11, lines 18-25; and column 17, line 64-column 18, line 40. It would have been *prima facie* obvious to one of ordinary

skill in the art at the time the claimed invention was made to utilize the different combinations of the therapeutic compositions for an autoimmune disease, as well as cancer for any primate animal. One of ordinary skill in the art would have been motivated to manufacture such a medicament in order to treat non-human primates such as a monkey companion animal, as well as other domestic or companion animals because the patent sets forth that the disclosed treatment of B cell lymphomas targeting the CD20 antigen is not limited to non-human primates, see patent '456, column 5, lines 7-10.

18. Claims 1, 2, 8, 9, 11, 12, 16, 19-22, 23, 24, 26, 30, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of Javid et al. (J. Clin Invest. 31(6): 604-10: June 1952). The teachings of patent #5,776,456 have been presented in the 102(e) rejection. U.S. Patent '456 does not teach a method for treating a B-cell or plasma-cell disorder in a domestic animal, such as a dog, cat or horse comprising administering to said animal a therapeutic composition comprising a pharmaceutically acceptable carrier an antibody component, wherein said component is an immunoconjugate composition including radionuclides and neutron-capturing boron addend.

However, U.S. Patent number 5,776,456 teaches the administration to human patients of therapeutic compositions comprising radiolabeled chimeric antibodies, wherein the radioisotope is yttrium 90 or diagnostic radionuclide indium 111; the combination of antibodies, for instance a dose imaging radiolabeled anti-CD20 antibody


(I2B8) and immunologically active, chimeric anti-CD20 antibody (C2B8); and chemotherapeutic agents such as doxorubicin and prednisone, see column 9, line 6-column 6, line 18; column 13, lines 25-33; and section V spanning columns 31 and 32. Javid teaches that neutron-capturing isotopes such as boron 10 can be administered for the treatment of neoplasms, see title and entire document. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the different combinations of the therapeutic compositions as anti-cancer medicaments for any primate animal in order to treat a B cell disorder in an animal. One of ordinary skill in the art would have been motivated to manufacture such a medicament in order to treat non-human primates such as a monkey companion animal, as well as other domestic or companion animals because the patent sets forth that the disclosed treatment of B cell lymphomas targeting the CD20 antigen is not limited to non-human primates, see patent '456, column 5, lines 7-10.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
07 September 2004